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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,461	09/10/2003	Christopher J. Calhoun	MA9758P	4950

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EXAMINER	
BARHAM, BETHANY P	

ART UNIT	PAPER NUMBER
1615	

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11/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,461	CALHOUN, CHRISTOPHER J.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/02/09, 11/19/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicant's Response and Claims filed on 09/21/09 is acknowledged. The IDS filed on 09/02/09 and 11/19/09 is also acknowledged. Claims 1, 3-11 and 22-24 are pending and rejected.

Declaration

The declaration under 37 CFR 1.132 filed 09/21/09 is insufficient to overcome the rejection of claims 1, 3-11 and 22-24 based upon US 2002/0001609 ('609) as set forth in the last Office action because: the declaration as filed is hearsay, as the declaration is signed by the attorney who did not invent the invention and the inventor has not signed the declaration. See MPEP 716.10: "When subject matter, disclosed but not claimed in a patent application filed jointly by S and another, is claimed in a later application filed by S, the joint patent or joint patent application publication is a valid reference available as prior art under 35 U.S.C. 102(a), (e), or (f) unless overcome by… an unequivocal declaration by S under 37 CFR 1.132 that he or she conceived or invented the subject matter disclosed in the patent or published application."

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation “material selected from the group consisting essentially of (a) poly-lactide polymer, (b) copolymer of lactides, and (c) poly-lactide polymer and a copolymer of lactides”, and the claim also recites “material being a poly-lactide polymer and a copolymer of lactides…being 70:30 poly(L-lactide-co-D,L-lactide)” which is the narrower statement of the range/limitation.

Similarly claim 3 recites the broad recitation "material selected from the group consisting essentially of (a) poly-lactide polymer, (b) copolymer of lactides, and (c) poly-lactide polymer and a copolymer of lactides", and the claim also recites "material being a poly-lactide polymer and the poly-lactidie polymer being poly-L-lactide" which is the narrower statement of the range/limitation.

MAINTAINED REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-10, 22-24 are rejected under 35 U.S.C. 102(a)/(e) as being anticipated by US 2002/0001609 ('609).

The applied reference has a common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claims are drawn to a method for promoting healing of damaged tissue after an open heart surgery, the method comprising: providing a substantially planar healing membrane, which is: (a) substantially-smooth on at least one side; (b) substantially uniform in composition; (c) about 10 microns to about 300 microns in thickness; (d) non-porous; (e) constructed from a resorbable polymer base material selected from the group consisting essentially of (a) poly-lactide polymer, (b) copolymer of lactides, and (c) poly-lactide polymer and a copolymer of lactides, the resorbable polymer base material being a poly-lactide polymer and a copolymer of lactides, and the poly-lactide polymer and a copolymer of lactides being 70:30 poly (L-lactide-co-D,L-lactide); and (f) adapted to be resorbed into the mammalian body within a period of approximately 18 to 24 months from an initial implantation of the membrane into the mammalian body; and placing the healing membrane adjacent to an opening in pericardial tissue of a patient so that the pericardial tissue surrounding the opening can regenerate over the membrane.

- '609 teaches a resorbable polylactide polymer scar tissue reduction barrier membrane and methods of application engineered to be absorbed into the body relatively slowly over time in order to reduce potential negative side effects with a thickness between 10-300 mircons (abstract).

- '609 teaches methods for attenuating the formation of post-surgical adhesions between the post-surgical site and adjacent surrounding tissue, specifically heart vessel repair is taught [0002, 0041].
- Figures 6-17 show that the membrane is smooth and uniform, nonporous, and are fully contourable accommodating different anatomical structures [0040, 0051].
- Polymers taught include polylactide and copolymers especially 70:30 poly (L-lactide-co-D,L-lactide) and that it can be shaped at the time of surgery [0038, 0043].
- '609 teaches that the membrane maintains structural integrity for a period in excess of 6 months and more preferably for at least one year before substantially degrading in order to achieve and optimize anti-scarring function [0044] (meeting the limitations of claims 1, 3, 7-9).
- '609 teaches that the thickness is 10-300 microns thick, preferably less than 200 microns, more preferably between 10-100 microns [0043] (meeting the limitations of claims 4-5).
- '609 teaches sterile packaging (abstract, [0052]) (meeting the limitations of claim 6).
- '609 teaches heat bonding the membrane to the tissue, wherein the membrane is wrapped around a structure and then heat joined to itself [0048-0049] (meeting the limitations of claim 10).

- '609 teaches that the membrane is used in heart vessel repair and that it can be contoured or shaped for different anatomical structures (see above [0040-0043, 0051]) meeting the limitations of claims 22-24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0001609 ('609) in view of US 6,211,217 ('217).

- '609 is taught above and teaches a membrane for reducing scar formation post-surgery.
- '609 does not teach an anti-scar agent, such as angiotensin antagonists, but does teach including a substance for cellular control such as a chemotactic, mitogenic growth factors and other growth factor that promote neoangiogenesis.
- '217 teaches methods of reducing fibrosis and adhesion formation after cardiac surgery including an AT1 receptor antagonist with administration from an implant (abstract, col. 3, lines 46-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '609 and '217. A skilled artisan would know how to substitute the

specific AT1 receptor antagonists which reduce adhesion formation and fibrosis after cardiac surgery into the product of '609 for reducing scar tissue and adhesions comprising a membrane and generically a substance. It is within the purview of the skilled artisan to substitute one active substance of '609 for the specific AT1 receptor antagonist of '217 which reduces adhesion formation and fibrosis.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-11 and 22-24 have been considered but are not persuasive since the declaration is not signed by the inventor and further is moot in view of the new grounds of rejection necessitated by applicants' amendments.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-61755. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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